OCT 7 - 2005

K052584

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92(c).

1. Device Name:	Magnetic Resonance Imaging Accessory
2. Proprietary Name:	1.5T 12 Channel Body Array
3. Classification:	Class II
4. Establishment Registration #:	1529041
5. Manufacture Facility Location:	USA Instruments, Inc. (A GE company) 1515 Danner Drive, Aurora, Ohio 44202, USA Telephone: 330-562-1000; Fax: 330-562-1422.
6. Performance Standard:	No applicable performance standards have been issued under Section 514 of the Food, Drug and Cosmetic Act.
7. Intended Use:	The USA Instruments 1.5T 12 Channel Body Array is intended to be used in the abdomen, pelvis and chest regions for 2D and 3D Magnetic Resonance imaging and Parallel body imaging.
8. Device Description:	The USA Instruments 1.5T 12 Channel Torso Coil is a 12-element coil with integrated preamplifiers that provides optimized geometry for parallel imaging. The coil is designed to provide imaging of the abdomen, pelvis and chest regions. This coil designed for use with the 1.5T Signa Excite MRI scanner, manufactured by General Electric Healthcare. The coil will be available with different connector configurations depending on the configuration of the scanner it will be used with.
9. Marketed Device:	1.5T 12 Channel Body Array
10. Comparison with Predicate:	The 1.5T 12 Channel Body Array is a modification of the existing cleared GE Healthcare 1.5T 8 Channel Torso Coil (K031209), with the main difference being the separation of the 12 individual elements into separate channels and a redesign of the coil connector to make it compatible with magnetic resonance scanners that have more then an 8 channel receive chain.
11. Summary of Studies:	Testing was performed to demonstrate that the design modifications to the 1.5T 12 Channel Body Array meet predetermined acceptance criteria.

Conclusion:

It is the opinion of USA Instruments that the 1.5T 12 Channel Body Array is substantially equivalent to the GE Healthcare 1.5T 8 Channel Torso Coil (K031209). Usage of the USA Instruments 1.5T 12 Channel Body Array does not result in any new potential hazards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 - 2005

Mr. Robert B. Smith
Quality Assurance/Regulatory Affairs
USA Instruments, Inc.
1515 Danner Drive
AURORA OH 44202

Re: K052584
Trade/Device Name: 1.5T 12 Channel Body Array
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: September 16, 2005
Received: September 20, 2005

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(k) Number (if known): K052584

Device Name: 1.5T 12 Channel Body Array

Indications for Use:

The USA Instruments 1.5T 12 Channel Body Array is intended to be used in the abdomen, pelvis and chest regions for 2D and 3D Magnetic Resonance imaging and Parallel body imaging.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801-109)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K052584